

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

IN RE: GERBER PRODUCTS COMPANY
HEAVY METALS BABY
FOOD LITIGATION

Master File No. 1:21-cv-269 (MSN/JFA)
Class Action

This Document Relates to ALL Cases

MEMORANDUM OPINION AND ORDER

This matter comes before the Court on Defendant Gerber Products Company's Motion to Dismiss Plaintiffs' Representative Class Action Complaint (Dkt. No. 132).¹ Upon consideration of the Motion, the memoranda in support thereof and in opposition thereto, the arguments of counsel at the hearing held on September 23, 2022, and for the reasons set forth below, the Motion is GRANTED.

I. CLAIMS AND PROCEDURAL HISTORY

On February 4, 2021, the U.S. House of Representatives Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, released a report titled "Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury," finding measurable levels of these heavy metals (hereinafter "Heavy Metals") in baby food products sold by Defendant Gerber Products Company ("Gerber"). RC ¶ 5. According to Plaintiffs, the report "criticized

¹ These Plaintiffs were selected by Plaintiffs' lead counsel to be Representative Plaintiffs in the Representative Class Action Complaint (Dkt. No. 112) (hereinafter "Representative Complaint" or "RC"). *See* (Dkt. No. 106). The RC does not displace any of the underlying complaints that have been consolidated before this Court. However, the rulings with respect to the RC will apply to all claims asserted in each Plaintiff's complaint unless a Plaintiff shows that a claim is materially different, legally or factually, from those considered in the RC. *See* (Dkt. No. 181), Tr. 18:07–25 (May 18, 2022).

Gerber for . . . not testing all ingredients and finished products for Heavy Metals, and for rarely testing for mercury in its baby foods.” *Id.*

The Subcommittee released a supplemental report on September 29, 2021, largely based on testing done by the State of Alaska’s Department of Environmental Health Laboratory. *Id.* ¶¶ 117–18. Relying on the Subcommittee’s February 2021 and September 2021 Reports (together the “Congressional Reports”), Plaintiffs filed the Representative Complaint on June 3, 2022 (Dkt. No. 112), alleging that the following products sold by Defendant Gerber (referred to herein as “Baby Food Product(s)”) contained harmful Heavy Metals at levels above what is considered safe for babies: Gerber Puffs (all flavors); Gerber Lil’ Crunchies (all flavors); Gerber Yogurt Melts (all flavors); Gerber 1st Foods (all flavors); Gerber 2nd Foods (all flavors); Gerber Cereals (all types); Gerber Juices (all flavors); Gerber Arrowroot Biscuits; Gerber Teether Wheels (all flavors); Gerber Yogurt Blends (all flavors); Gerber Fruit & Veggie Melts (all types and flavors); Gerber Graduates Mealtime for Toddler (all flavors); and Gerber Diced Carrots Veggie Pick-Ups. *See RC ¶ 1.*

Plaintiffs allege the amount of Heavy Metals in the Baby Food Products was harmful to their children. *See id. ¶ 8.* In support, Plaintiffs rely on standards set by the Food and Drug Administration (“FDA”), World Health Organization, Environmental Protection Agency (“EPA”), the Congressional Reports, and on reports authored by industry groups. *See, e.g., id. ¶¶ 52–53.* With respect to lead, the RC explains that the EPA, the Centers for Disease Control and Prevention, and others agree there is no established “safe level of lead . . . in a child’s blood.” *Id. ¶ 54.* The RC points to FDA limits for maximum daily intake of lead from food of 3 micrograms (“ μg ”) for children and 12.5 μg for women of childbearing age, and a maximum limit of 5 parts per billion (“ppb”) for lead in bottled water. *Id. ¶¶ 55–56.* As to arsenic, the RC states the FDA has set a

maximum level of 10 ppb for arsenic in drinking water and a limit of 100 ppb for inorganic arsenic in infant rice cereal. *Id.* ¶ 52. The Supplemental Report found, among other things, that Gerber's rice cereals "tested up to 116 ppb inorganic arsenic," which is above the FDA's 100 ppb standard. *Id.* ¶¶ 118–19. With respect to cadmium, the RC explains the FDA and EPA have set a maximum allowable limit of 5 ppb for cadmium in bottled water and drinking water. *Id.* ¶ 63. Lastly, as to mercury, the RC states the FDA has set a limit of 2 ppb for mercury in bottled water, while the EPA has set a limit of 2 ppb for drinking water. *Id.* ¶ 71.

Plaintiffs allege the Baby Food Products contain materially misleading statements or omissions because

Gerber failed to disclose on its packaging that (1) the Gerber Baby Food Products contain or were at material risk of containing harmful Heavy Metals; (2) Gerber inadequately tested, or never tested, for all Heavy Metals in all the ingredients it uses and/or its finished products; and that (3) when Gerber does set internal standards, they allow for the sale of Baby Food Products with Heavy Metals in amounts that could cause harm to babies and children and at times, the Baby Food Products have failed to meet even those internal standards.

Id. ¶ 11. Had Gerber disclosed the foregoing material facts, Plaintiffs claim they "would have sought alternative options and would not have purchased the Gerber Baby Food Products." *Id.* Further, Plaintiffs allege they were injured because they "did not receive the benefit of their bargain and thus overpaid for" the Baby Food Products. *Id.* Accordingly, Plaintiffs seek injunctive relief and monetary damages for Defendant's alleged material omissions. *Id.* at p. 96.²

² Specifically, Plaintiffs request various forms of injunctive relief including an order (1) enjoining Defendant from "selling the Baby Food Products until the harmful Heavy Metals are removed or reduced to nondetectable levels and/or full disclosure of the presence of such prominently appears on all packaging"; (2) "requiring Defendant to establish sourcing and control protocols, consult with an independent auditor, and conduct compliance testing"; (3) "enjoining Defendant from selling its Baby Food Products in any manner suggesting or implying that they are healthy, nutritious, and safe for consumption unless Defendant adequately tests for Heavy Metals and ensures that the Heavy Metals are no longer present or reduced to nondetectable levels"; and (4) "requiring Defendant to engage in a corrective advertising campaign and to engage in any further necessary affirmative injunctive relief, such as recalling existing

Plaintiffs collectively assert the following thirteen causes of action in their Representative Complaint:

Count I: breach of implied warranty (on behalf of Plaintiffs and the class or, in the alternative, the State classes) (RC ¶¶ 170–87);³

Count II: fraudulent concealment – fraud by omission (on behalf of Plaintiffs and the class or, in the alternative, the State classes) (*id.* ¶¶ 188–200);

Count III: quasi contract/unjust enrichment (on behalf of Plaintiffs and the class or, in the alternative, the State classes) (*id.* ¶¶ 201–09);

Count IV: violation of California’s Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.* (on behalf of Plaintiffs Christopher Craig, Deandra Bryant, Mayra Verduzco, and the California class) (*id.* ¶¶ 210–26);

Count V: violations of California’s False Advertising Law, Cal. Bus. & Prof. Code § 17500, *et seq.* (on behalf of the California Plaintiffs and the California class) (*id.* ¶¶ 227–39);

Count VI: violation of California’s Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.* (on behalf of the California Plaintiffs and the California class) (*id.* ¶¶ 240–56);

Count VII: violation of the Song-Beverly Consumer Warranty Act, Cal. Civ. Code § 1790, *et seq.* (on behalf of the California Plaintiffs and the California class) (*id.* ¶¶ 257–76);⁴

Count VIII: violation of Florida’s Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.* (on behalf of Plaintiffs Renee Bryan, Jennifer Gaetan, Vanessa Inoa, and the Florida class) (*id.* ¶¶ 277–89);

Count IX: violation of Illinois’ Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1, *et seq.* (on behalf of Plaintiff Charlotte Willoughby and the Illinois class) (*id.* ¶¶ 290–306);

Count X: violation of New York’s Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law § 349 (on behalf of Plaintiffs Angelique Velez, Danielle Visconti, and the New York class) (*id.* ¶¶ 307–24);

products.” RC at pp. 96–97. Plaintiffs have abandoned their request for “an order recalling the [Baby Food] Products or a declaration that the Products are adulterated or unsafe.” Pl. Opp. (Dkt. No. 145) at 6. Further, it appears that Plaintiffs have abandoned their request for disgorgement of revenues and profit. *See* RC at p. 97.

³ In Plaintiffs’ Opposition to Defendant’s Motion to Dismiss, Plaintiffs agreed to dismiss their breach of implied warranty claim. Pl. Opp. at 6 n.4.

⁴ In Plaintiffs’ Opposition to Defendant’s Motion to Dismiss, Plaintiffs agreed to dismiss their Song-Beverly Consumer Warranty Act claim. Pl. Opp. at 6 n.4.

Count XI: violation of New York's False Advertising Act, N.Y. Gen. Bus. Law § 350 (on behalf of Plaintiffs Angelique Velez, Danielle Visconti, and the New York class) (*id.* ¶¶ 325–40);

Count XII: violation of Texas' Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. & Com. Code § 17.41, *et seq.* (on behalf of Plaintiffs Jessica Moore, Janice Wilson, and the Texas class) (*id.* ¶¶ 341–58); and

Count XIII: violations of Virginia's Consumer Protection Act, Va. Code Ann. § 59.1-196, *et seq.* (on behalf of Plaintiffs and the class) (*id.* ¶¶ 359–77).

On July 8, 2022, Defendant filed a motion to dismiss Plaintiffs' claims on several grounds, two of which are the focus of the Court's analysis: (1) Plaintiffs fail to state a plausible claim that they suffered an economic injury and that they are entitled to injunctive relief, and (2) the FDA should determine what foods are unsafe under the primary jurisdiction doctrine. As explained more fully below, Defendant's Motion to Dismiss will be granted.⁵

II. LEGAL STANDARD

A. RULE 12(b)(6)

The Federal Rules of Civil Procedure require a complaint to set forth "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (cleaned up). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (cleaned up). Importantly, in making this determination, a district court must "accept as true all well-pled facts in the complaint and construe them in the light most favorable to [the plaintiff]." *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 632 n.1 (4th Cir. 2015).

⁵ Because the Court dismisses the Representative Complaint on the threshold issue of standing, and in the alternative, primary jurisdiction, it need not address Defendant's other proposed grounds for dismissal here.

However, to survive a motion to dismiss, the complaint must “state[] a plausible claim for relief” that “permit[s] the court to infer more than the mere possibility of misconduct” based upon “its judicial experience and common sense.” *Ashcroft*, 556 U.S. at 679. In this regard, while a plaintiff is not required to plead facts that constitute a *prima facie* case in order to survive a motion to dismiss, *see Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 510–15 (2002), “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Bell Atl. Corp.*, 550 U.S. at 555. Further, for a plaintiff to prevail, the complaint must do more than allege the plaintiff’s entitlement to relief; it must “show such an entitlement with its facts.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009) (cleaned up).

B. STANDING

While Defendant focuses on Plaintiffs’ failure to plead injury as an element of their claims, injury is also a requirement for standing—an issue the Court may raise *sua sponte* “as a matter of the case-or-controversy requirement associated with Art. III.” *Juidice v. Vail*, 430 U.S. 327, 331 (1977); *see Buscemi v. Bell*, 964 F.3d 252, 258 (4th Cir. 2020) (a court must ensure it has subject matter jurisdiction, and as such, may address standing *sua sponte*). Because Plaintiffs must establish standing to maintain an action in federal court, the Court first considers whether Plaintiffs have alleged an injury for purposes of Article III standing, taking care to “separate [its] standing inquiry from any assessment of the merits of [Plaintiffs’] claim.” *See Cottrell v. Alcon Labs.*, 874 F.3d 154, 162 (3d Cir. 2017).⁶

As the party seeking to invoke federal jurisdiction, Plaintiffs bear the burden of establishing standing. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). Similar to a review of

⁶ Defendant asserts it raised injury under Rule 12(b)(6) rather than as a challenge to standing under Rule 12(b)(1) because this would “allow the Court to rule on all of [Plaintiffs’ claims].” Hr. Tr. (Dkt. No. 198) 57:25–58:09. The Court disagrees and concludes, as discussed below, that it can rule on all claims based on Article III standing.

a complaint for failure to state a claim, courts “must accept as true all material allegations of the complaint and must construe the complaint in favor” of plaintiffs when determining whether plaintiffs have standing. *Denney v. Deutsche Bank AG*, 443 F.3d 253, 263 (2d Cir. 2006). The threshold, however, to demonstrate standing is lower than that required to state a claim. *Ross v. Bank of Am., N.A. (USA)*, 524 F.3d 217, 222 (2d Cir. 2008); cf. *Buscemi*, 964 F.3d at 266 (finding injury in fact for Article III standing, but dismissing for failure to state a claim). “Moreover, the fact that an injury may be outweighed by other benefits, while often sufficient to defeat a claim for damages, does not negate standing.” *Ross*, 524 F.3d at 222.

To establish standing, Plaintiffs must adequately plead three elements: (1) an injury in fact, (2) a “causal connection between the injury and the conduct complained of,” and (3) that it is “likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Lujan*, 504 U.S. at 560–61 (cleaned up). In the class action context, at least one named plaintiff must satisfy all three requirements. *O’Shea v. Littleton*, 414 U.S. 488, 494 (1974). The Court’s analysis focuses on the first and most important of these three elements: the injury in fact. See *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Liab. Litig.* (“*In re J&J*”), 903 F.3d 278, 284 (3d Cir. 2018).

Demonstrating an injury in fact requires plaintiffs to allege three sub-elements: (a) plaintiffs must show they suffered “an invasion of a legally protected interest,” (b) the alleged injury must be “concrete and particularized,” and (c) the alleged injury must be “actual or imminent, not conjectural or hypothetical.” *Lujan*, 504 U.S. at 560 (cleaned up). “[T]he injury in fact test requires more than injury to a cognizable interest. It requires that the party seeking review be himself among the injured.” *Id.* at 563.

III. ANALYSIS

Plaintiffs seek relief in the form of monetary damages and injunctive action. Because Plaintiffs must demonstrate they have “standing for *each* type of relief sought,” *see In re J&J*, 903 F.3d at 284 (cleaned up), the Court will assess whether Plaintiffs have alleged an injury in fact sufficient to seek these two categories of relief.

A. MONETARY DAMAGES

In their opposition to Defendant’s motion to dismiss, Plaintiffs make clear they do not seek to establish standing on the basis of personal injury, *i.e.*, an increased risk of adverse health effects as a result of consuming the Baby Food Products. *See Pl. Opp.* (Dkt. No. 145) at 19 n.14 (“Plaintiffs do not allege personal injuries and none of their claims or damage theories require them to do so. Nor are they required to allege that the specific products they bought were unfit for human consumption.”); *id.* at 2 (“Plaintiffs are not required to allege a personal injury”); *id.* at 6 (“Plaintiff [sic] do not seek an order recalling the Products or a declaration that the Products are adulterated or unsafe.”); *id.* at 7 n.5 (“Plaintiffs’ claims do not turn on proving whether Gerber’s products were safe”). Rightfully so, as Plaintiffs must plead a credible or substantial threat to their health or that of their children and such threat “must be certainly impending to constitute injury in fact.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 401 (2013) (cleaned up); *see Kimca v. Sprout Foods, Inc.* (“*Kimca I*”), No. 2:21-cv-12977-SRC-JSA, 2022 WL 1213488, at *5 (D.N.J. Apr. 25, 2022) (finding FDA benchmarks and other data cited by plaintiffs were too speculative and arbitrary to conclude that plaintiffs plausibly alleged the baby food products were unsafe); *Herrington v. Johnson & Johnson Consumer Cos., Inc.*, No. C 09–1597 CW, 2010 WL 3448531, at *5 (N.D. Cal. Sept. 1, 2010). As Plaintiffs well know, “fear and apprehension about a possible future

physical or medical consequence . . . is not enough to establish an injury *in fact.*" *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 636 (3d Cir. 1996) (Wellford, J., concurring) (cleaned up).

Plaintiffs' sole theory of injury in fact, then, is economic harm resulting from their purchase of a product that was "worthless or worth less" than the purchase price due to Defendant's material omissions. RC ¶ 339. Courts have recognized various and sometimes overlapping theories for pleading economic injury—including a benefit of the bargain theory,⁷ a price premium theory,⁸ and an alternative product theory⁹—but underlying each approach is the basic principle that economic harm results when the purchase price of a product exceeds the actual value of the product after taking into account a defendant's improper actions.

This is where Plaintiffs' argument runs afoul of logic: to establish the diminished value of the Baby Food Products—a necessary predicate to show economic harm—Plaintiffs allege the Baby Food Products were worth less than the purchase price, not because they failed to perform as intended or were otherwise defective, but because they contained or were at risk of containing Heavy Metals. Those Heavy Metals, Plaintiffs assert, "are indisputably harmful to children and can result in serious developmental and other health problems," and Plaintiffs would not have purchased the Baby Food Products had they known the risks. Pl. Opp. at 21 (citing RC ¶¶ 45, 73); *id.* at 22 (Heavy Metals "can lead to harm including IQ loss, attention deficits, and other learning and behavioral impacts among children") (citing RC ¶¶ 45–72). In other words, Plaintiffs' *only* purported basis for economic injury stems from their allegation that the Baby Food Products posed a threat of future harm—an allegation that Plaintiffs explicitly disavow in the context of personal injury. As discussed below, Plaintiffs fail to allege sufficient facts to support a finding of economic

⁷ See, e.g., *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1084 (11th Cir. 2019).

⁸ See, e.g., *Duran v. Henkel of Am., Inc.*, 450 F. Supp. 3d 337, 350 (S.D.N.Y. 2020).

⁹ See, e.g., *In re J&J*, 903 F.3d 278, 282–83 (3d Cir. 2018).

injury for the same reasons they cannot support a personal injury claim: there is no “actual or imminent” injury alleged. *Lujan*, 504 U.S. at 560.

Plaintiffs claim that, due to Defendant’s material omissions, they did not “receive the benefit of their bargain and thus overpaid for the Gerber Baby Food Products.” RC ¶ 11. Plaintiffs also assert the inverse: that “Gerber’s omissions created a ‘price premium’ for the Products and thus Plaintiffs did not receive the ‘benefit of their bargain.’” Pl. Opp. at 16. The Court will address each potential theory of economic injury—benefit of the bargain and price premium—in turn.

1. Benefit of the Bargain

A person is deprived of the benefit of her bargain when, due to a seller’s deceptive act, unfair practice, or misrepresentation, she purchases a product that is in fact worth less than the represented value. See *In re Devotion Assocs., Ltd.*, 86 F.3d 1149, 1996 WL 265990, at *2 (4th Cir. 1996) (unpublished table decision); *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1084 (11th Cir. 2019). Typically, when the defective or misrepresented product is a durable good still in plaintiff’s possession, it retains some value and plaintiff’s “benefit-of-the-bargain damages are less than the entire purchase price of the product.” *Debernardis*, 942 F.3d at 1084; *In re Lumber Liquidators Chinese-Manufactured Flooring Prods. Mkt., Sales Pracs., & Prods. Liab. Litig.* (“*In re Lumber Liquidators*”), No. 1:15-md-2627, 2017 WL 2646286, at *5 (E.D. Va. June 20, 2017); *In re Fruit Juice Prods. Mktg. & Sales Pracs. Litig.*, 831 F. Supp. 2d 507, 513 (D. Mass. 2011). But, when a plaintiff purchases a consumable good and uses it to her benefit, there is no economic injury unless plaintiff alleges the product “failed to work for its intended purpose or was worth objectively less than what one could reasonably expect.”¹⁰ *Koronthaly v. L’Oreal USA, Inc.*, 374

¹⁰ The Court notes that a benefit of the bargain measure of damages arises out of contract law, whereas a mislabeling claim arises out of tort law. See *Debernardis*, 942 F.3d at 1085; *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. 2002); *Koronthaly v. L’Oreal USA, Inc.*, 374 F. App’x 257, 259 (3d Cir. 2010) (finding lipstick purchases were

F. App'x 257, 259 (3d Cir. 2010); *Herrington*, 2010 WL 3448531, at *4; see *Estrada v. Johnson & Johnson Consumer Cos., Inc.*, Civ. Action No. 16-7492 (FLW), 2017 WL 2999026, at *9 (D.N.J. July 14, 2017) *aff'd sub nom. In re J&J*, 903 F.3d 278, 284 (3d Cir. 2018); *James v. Johnson & Johnson Consumer Cos.*, No. 10-cv-03049 (DMC)(JAD), 2011 WL 198026, at *2 (D.N.J. Jan. 18, 2011).

Plaintiffs claim Defendant deceptively led them to believe the Baby Food Products were safe¹¹ and, had they known the Baby Food Products contained or were at a material risk of containing harmful Heavy Metals, they would not have purchased them. *See, e.g.*, RC ¶ 339. Plaintiffs contend that Defendant's failure to disclose the presence of Heavy Metals, or risk thereof, rendered the Baby Food Products "worthless or worth less than the price they paid" and thereby deprived Plaintiffs of the benefit of their bargain. *Id.* Defendant counters that Plaintiffs were able to use the Baby Food Products as intended and without suffering any adverse consequences—essentially arguing that, in so doing, Plaintiffs received the full benefit of their bargain—and that unspecified, vague assertions of the Baby Food Products' diminished value are insufficient to demonstrate economic harm. *See* Def. Mem. (Dkt. No. 133) at 24.

The Third Circuit considered a similar argument in *In re J&J*. There, plaintiff Estrada claimed a benefit of the bargain theory of economic injury by alleging that Johnson & Johnson engaged in deceptive advertising when it failed to disclose that a woman's perineal use of its baby

not made pursuant to a contract, and therefore plaintiff could not have been denied the benefit of any bargain). Although no such contract between Plaintiffs and Defendant exists here, the Court nevertheless considers whether Plaintiffs plausibly allege an economic injury in fact based on the Baby Food Products' failure to perform as intended.

¹¹ This belief is based on "the famous 'Gerber Baby' logo" and other "indications" (such as Gerber's packaging claims that certain products support "brain development and learning ability" or are "made with real fruit" or "whole grains"), which "conveyed to parents . . . that the Gerber Baby Food Products are safe and suitable for consumption by babies and young children." RC ¶ 4.

powder “can lead to an increased risk of developing ovarian cancer.” *In re J&J*, 903 F.3d at 281.¹²

Estrada argued she did not receive the benefit of her bargain because she was promised a baby powder that was “safe” to use, and she would not have bought the product had she known of the health risks. *Id.* at 281–83. Estrada did not allege she was at an increased risk of adverse health effects under a personal injury claim; rather, she argued her purchase—based on J&J’s deceptive and unfair business practices—alone constituted an injury in fact. *Id.* at 287.

The Third Circuit rejected this argument. To allege an economic injury merely from purchasing a product, Estrada was required to plead with specific facts that the baby powder she purchased was worth less than what she paid. *Id.* at 287–88. Despite Estrada’s allegations that the baby powder was unsafe, she omitted any allegation that *she* developed ovarian cancer or that *she* was at risk of developing ovarian cancer in the future. *Id.* at 289. “Estrada’s references to Baby Powder being unsafe *as to others* are not relevant to determining whether Estrada has standing *herself*.” *Id.* Because Estrada did not allege a risk of physical harm or seek recovery of personal injury damages, the court concluded the baby powder must have been “*safe as to her*.” *Id.* In other words, Estrada received exactly that for which she bargained: she purchased baby powder that was not “unsafe,” *id.* at 291, she consumed the product in its entirety, and there were no allegations the baby powder failed to perform as marketed (*i.e.*, “designed to gently absorb excess moisture” and keep “skin feeling soft, fresh and comfortable”). *Id.* at 281. Thus, Estrada could not establish injury under a benefit of the bargain theory of economic harm.

Like plaintiffs in *In re J&J* and as noted above, *see supra* p. 8, Plaintiffs do not allege the Baby Food Products were unsafe as to them. The Representative Complaint certainly discusses the

¹² “In support of her allegations regarding the increased cancer risk associated with Baby Powder, Plaintiff cites numerous clinical studies that have been conducted since 1961. Plaintiff alleges that since at least 1982, Defendants have been aware of the studies associating talcum powder with an elevated risk of ovarian cancer.” *Estrada*, 2017 WL 2999026, at *1 (cleaned up).

dangers to human health from exposure to Heavy Metals, especially to children and infants, *see generally* RC ¶¶ 42–75; however, it contains no allegations the Baby Food Products were adulterated, recalled, or the cause of any reported injuries.¹³ *See In re Fruit Juice Prods. Mktg. & Sales Pracs. Litig.*, 831 F. Supp. 2d at 512; *Herrington*, 2010 WL 3448531, at *20 (defendant’s alleged failure to disclose the presence of possible carcinogens and unsafe contaminants in children’s bath products did not create an economic injury because plaintiffs did not allege the levels of contaminants were unsafe). Nor does the Representative Complaint allege Plaintiffs’ children are at imminent risk of developing any specific ailment in the future because they consumed the Baby Food Products. Indeed, Plaintiffs concede “[their] claims do not turn on proving whether Gerber’s products were safe.” Pl. Opp. at 7 n.5. Accordingly, this Court must conclude the Baby Food Products were “safe as to them.”

Further, Plaintiffs have not alleged the Baby Food Products failed to provide Plaintiffs’ children with nourishment or to otherwise perform as intended. To state a concrete and particularized injury, a plaintiff must do more than allege she did not receive the benefit she *thought* she was obtaining. “The plaintiff must show that she did not receive a benefit for which she actually *bargained*.” *McGee v. S-L Snacks Nat'l*, 982 F.3d 700, 706 (9th Cir. 2020); *see also Herrington*, 2010 WL 3448531, at *5 (N.D. Cal. Sept. 1, 2010) (“[p]laintiffs complain about a consumable good that they used to their benefit”). “Without alleging that a product failed to perform as advertised, a plaintiff has received the benefit of [her] bargain and has no basis to

¹³ The closest Plaintiffs come to making such an allegation is with respect to Defendant’s rice cereals, which “tested [at levels] up to 116 ppb inorganic arsenic,” and which Defendant did not recall despite having “nearly identical” levels to Beech-Nut’s recalled rice cereals. RC ¶ 119. Yet, in their opposition to Defendant’s motion to dismiss, Plaintiffs clarified that they “do not allege that Gerber’s Products are adulterated, and their claims do not depend on such a showing.” *See* Pl. Opp. at 14; *id.* at 7. Thus, Plaintiffs specifically disavow any allegation that the Baby Food Products are unsafe or otherwise unfit for sale and consumption, instead basing their claims only “on Gerber’s failure to disclose material facts that consumers, including parents, *would want to know* when deciding what foods to buy and feed to their kids.” *Id.* at 7 (emphasis added).

recover purchase costs.” *See Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 176 (D.D.C. 2003). Although Plaintiffs never explicitly address whether they or their children consumed the Baby Food Products,¹⁴ the Court can infer the Baby Food Products performed as intended based on Plaintiffs’ acknowledgment that they purchased said Products repeatedly and “frequently.” *See, e.g.*, RC ¶ 16 (“Plaintiff Bryant purchased these products frequently from approximately December 2020 through February 2021.”).

Here, Plaintiffs paid for safe and healthy food for their children and apparently received just that—the benefit of their bargain. Accepting the pleadings as alleged, Plaintiffs’ only complaint is that the Baby Food Products’ levels of Heavy Metals are “unsatisfactory to [them].” *Koronthaly v. L’Oreal USA, Inc.*, No. 07-cv-5588, 2008 WL 2938045, at *5 (D.N.J. July 2, 2008), *aff’d*, 374 F. App’x 257 (3d Cir. 2010). Without more, such an assertion does not amount to a concrete and particularized injury.¹⁵ As such, this Court finds that Plaintiffs’ benefit of the bargain theory of economic harm is insufficient to establish an injury in fact for the purposes of Article III standing.

2. Price Premium

“One method of demonstrating actual injury in the consumable goods context is by showing that the plaintiff paid a ‘price premium’—that is, as a result of the defendant’s deception,

¹⁴ This is likely because an admission would negate one or the other of Plaintiffs’ conflicting economic injury claims: if the Product *was not* consumed, there would be no risk of an adverse health consequence that arguably diminishes its value; but, if the Product *was* consumed, then Plaintiffs would have already received its full value because it performed as intended.

¹⁵ This is particularly true where a plaintiff’s theory of harm is based on a defendant’s alleged misrepresentation by omission. *See Estrada*, 2017 WL 2999026, at *6 (plaintiff’s benefit of the bargain theory of economic harm based on an omission failed to state a claim where defendant was not under any obligation to disclose the risks associated with the baby powder on the product’s labels or advertisements). While Plaintiffs allege Defendant was “in a special position of public trust as a manufacturer of baby foods,” RC ¶ 192, they have not identified an affirmative duty or legal obligation, under the FDCA or any other law, requiring Defendant to disclose the presence of Heavy Metals in its Baby Food Products.

the plaintiff paid more for a product than he otherwise would have.” *Eidelman v. Sun Prod. Corp.*, No. 21-cv-1046, 2022 WL 1929250, at *1 (2d Cir. June 6, 2022) (citing *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015)); *see Duran v. Henkel of Am., Inc.*, 450 F. Supp. 3d 337, 350 (S.D.N.Y. 2020) (under a price premium theory, a plaintiff may plead an economic injury by alleging “an overpayment, or price premium, whereby a plaintiff pays more than she would have but for the deceptive practice”). It is not enough to allege that a plaintiff would not have purchased the product but for a defendant’s deception; “a plaintiff must show that she did not receive the full value of her purchase.” *Naimi v. Starbucks Corp.*, 798 F. App’x 67, 70 (9th Cir. 2019). Typically, a company markets a product as having a “unique quality,” allowing the company to charge a higher price, but the purchaser later learns the product did not, in fact, have the marketed quality. *Duran*, 450 F. Supp. 3d at 350. The economic injury is then calculated as the unfair “premium” the purchaser was unlawfully induced to pay. *In re J&J*, 903 F.3d at 283. While identifying the prices of competing products would strengthen a plaintiff’s allegation of injury, “the failure to do so is not fatal.” *Goldemberg*, 8 F. Supp. 3d at 482.

Plaintiffs invoke the price premium theory for the first time in their opposition to Defendant’s motion to dismiss, claiming that “Gerber’s omissions with respect to Heavy Metals permitted Gerber to command a higher price in the marketplace for its products than it otherwise would have, causing Plaintiffs to overpay and robbing them of the benefit of their bargain.” Pl. Opp. at 29. Plaintiffs’ basis for alleging a price premium theory of economic harm is therefore identical to their basis for alleging a benefit of the bargain theory: “Gerber’s product packaging was false, deceptive, and misleading to reasonable consumers because Gerber failed to disclose material facts,” and, had Defendant made such disclosures, Plaintiffs “would have sought alternative options and would not have purchased the Gerber Baby Food Products.” RC ¶¶ 10–11.

Plaintiffs likewise contend that the measure of damages under the price premium theory is substantially similar to that under the benefit of the bargain theory, *i.e.*, the difference in value between the Baby Food Products as represented and what Plaintiffs received. Pl. Opp. at 16; *In re Lumber Liquidators*, 2017 WL 2646286, at *5 (citing *Carriuolo v. Gen. Motors Co.*, 823 F.3d 977, 986–87 (11th Cir. 2016)). However, Plaintiffs assert they are not required to “specify the exact amount of overpayment” at this stage. Pl. Opp. at 19.

Without addressing whether Plaintiffs oversimplify or conflate these two theories of economic injury, the Court agrees that, at essence, both theories aim to redress a purchaser’s overpayment—caused by a seller’s deceptive representation—for a product that underperformed. As a result, Plaintiffs fall short of establishing a price premium theory of economic harm for the same reasons they do not successfully articulate a benefit of the bargain theory: they fail to allege any facts showing the value of Baby Food Products was less than what Defendant falsely represented or what Plaintiffs believed it to be at the time of purchase. While the Court’s analysis under the benefit of the bargain theory focused on whether Plaintiffs sufficiently allege the Baby Food Products “failed to work for its intended purpose,” the foregoing discussion of the price premium theory focuses on whether Plaintiffs sufficiently allege the Products “[were] worth objectively less than what one could reasonably expect.” *Koronthaly*, 374 F. App’x at 259.

Plaintiffs rely heavily on *In re Lumber Liquidators*, in which plaintiffs alleged the defendant’s misleading statements—regarding the safety of its flooring and compliance with applicable regulations concerning formaldehyde emissions for composite wood products—allowed it to sustain inflated prices. 2017 WL 2646286, at *3. On summary judgment, the Court found plaintiffs’ theory was akin to a benefit of the bargain theory of injury whereby “[t]he measure of damages . . . is the difference at the time and place of acceptance between the value of

the goods accepted and the value they would have had if they had been as warranted.” *Id.* at *5 (quoting *Carriuolo*, 823 F.3d at 986–87).

To demonstrate the difference in price, plaintiffs alleged that “once the truth came out about the dubious reliability of the [regulatory] certifications, the products’ value plummeted to zero, as it was pulled from the market, never to be sold again.” *Id.* (cleaned up). Essentially, plaintiffs argued that the products would have been priced lower if consumers had known the composite flooring did not accord with regulations and “[p]laintiffs would have, in turn, paid a lower price than they did.” *Id.*

The court found plaintiffs’ theory of injury was adequately supported by facts and expert opinions sufficient to confer standing at the summary judgment stage.¹⁶ *Id.* at *6; see, e.g., *id.* at *3 (“Plaintiffs have produced evidence sufficient, when viewed most favorably to them, for a fact finder to reasonably conclude that Lumber Liquidators, including its top management, were on notice that certain of its Products were not CARB compliant as advertised.”). Contrary to Plaintiffs’ assertions, the Court did not blindly “accept[] the plaintiffs’ commonsense testimony that they would not have paid what they did to incur such a risk [caused by formaldehyde].” Pl. Opp. at 18.¹⁷

¹⁶ Although *In re Lumber Liquidators* was decided at the summary judgment stage, it nevertheless supports finding a lack of standing in this case. “At the summary judgment stage, the party invoking federal jurisdiction must have at least alleged specific facts that, taken as true, demonstrate the party suffered an injury in fact.” *Cnty. of Mille Lacs v. Benjamin*, 262 F. Supp. 2d 990, 995 (D. Minn. 2003), *aff’d*, 361 F.3d 460 (8th Cir. 2004) (internal quotations omitted). By contrast, the standard on a motion to dismiss requires only that a complaint “contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft*, 556 U.S. at 678 (cleaned up).

¹⁷ In finding Article III standing, the Court relied on the Eleventh Circuit’s decision in *Carriuolo v. General Motors Co.*, which held that a manufacturer’s misrepresentations regarding a vehicle’s safety rating allowed the manufacturer to “command a price premium and to overcharge customers systematically.” *Id.* at *6 (discussing *Carriuolo*, 823 F.3d at 986–87). In other words, plaintiffs’ standing in *Carriuolo* and in *In re Lumber Liquidators* rested on an injury in fact derived from an *affirmative misrepresentation* that had a direct economic impact on the value of the product sold: in *Carriuolo*, that the vehicles had a perfect safety rating, and in *In re Lumber Liquidators*, that the flooring was CARB compliant. This allowed each court to calculate the measure of economic harm as the difference between the market value of the product with the affirmatively-represented “unique quality” and without. Here, the Court is being asked

In the instant case, Plaintiffs have not “allege[d] facts that affirmatively and plausibly suggest that . . . [they have] standing to sue” under a price premium theory of economic injury because Plaintiffs fail to allege any facts substantiating their conclusory allegations that would permit the court to determine the economic value of their alleged lost benefit without resorting to mere conjecture. *See Bloomberg Fin. L.P. v. UBS AG*, 358 F. Supp. 3d 261, 277 (S.D.N.Y. 2018). While Plaintiffs are not “required to allege the *exact* value of [their] economic injury at the pleading stage,” they are required, even at this stage, to “set forth sufficient factual allegations that, if proven true, would permit a fact finder to determine that [they] suffered at least *some* economic injury,” *i.e.*, that the product was worth less than the purchase price. *In re J&J*, 903 F.3d at 287. Although Plaintiffs allege they “overpaid” for Defendant’s Baby Food Products, *see RC ¶ 11*, they do not allege how much they paid for the Baby Food Products, how much they would have paid had the material facts been disclosed, or any other details regarding the alleged price premium. *See Sabo v. Wellpet, LLC*, 250 F. Supp. 3d 332, 337 (N.D. Ill. 2017) (finding no price premium where plaintiffs failed to allege they “*in fact*” paid more for pet food because of “Made in the USA” designation, or that pet food without the designation was less expensive); *Naimi*, 798 F. App’x at 70 (“The bare recitation of the word ‘premium’ does not adequately allege a cognizable injury.”).

Plaintiffs’ attempt to point to comparable products on the market falls short. The Representative Complaint states that there are other manufacturers, “such as Nature’s One, Cerebelly, Bobbie, Else Nutrition, and Once Upon a Farm,” that have received the Clean Label Project’s Purity Award for not having “measurable levels of Heavy Metals” in their baby food products. RC ¶¶ 135–37; Sur-Reply (Dkt. No. 191) at 3. However, Plaintiffs do not allege these

to calculate the alleged economic harm based on an *omission*, without any alleged facts regarding the market value of Baby Food Products with and without the omission.

products contain the disclosures Plaintiffs seek or that the products' price or value is correlated to their Heavy Metal content. “[W]ithout any factual foundation to moor [Plaintiffs’] subjective estimation of the products’ worth,” Plaintiffs’ allegations are “too speculative to support an inference of actual damages.” *See Sabo*, 250 F. Supp 3d at 337.

Two other district courts have considered standing in relation to substantially similar allegations arising from the Congressional Reports and arrived at differing conclusions. With little explanation, the Northern District of California found standing, noting that “[t]he Ninth Circuit’s decision in *McGee v. S-L Snacks Nat'l*, 982 F.3d 700 (9th Cir. 2020)[,] does not preclude such a finding.” *In re Plum Baby Food Litig.*, No. 4:21-cv-913 (Dkt. No. 125), at 1 (N.D. Cal. Jan. 12, 2022). The Ninth Circuit in *McGee* declined to opine on “whether a plaintiff who consumes a product can nonetheless be deprived of the benefit of her bargain or have overpaid for the product.” 982 F.3d at 708 n.6. The Court agrees with the Northern District of California that the Ninth Circuit’s decision in *McGee* does not, by itself, preclude finding an injury in fact where Plaintiffs may have entirely consumed the Baby Food Products. *In re Plum Baby Food Litig.*, No. 4:21-cv-913 (Dkt. No. 125), at 1. However, the Court finds the District of New Jersey’s decision in *Kimca I* more persuasive.

In *Kimca I*, the court concluded plaintiffs failed to allege an economic injury because (1) they did not allege their children were at risk of harm because of the increased chance the baby food may contain heavy metals, 2022 WL 1213488, at *6; (2) they did not allege the baby food failed to provide safe, nutritious food to their children, *id.* at *8–9; and (3) they did not allege the products failed to comply with any regulatory standards applicable to baby food, *id.* at *5–7. For the reasons stated above, Plaintiffs have similarly failed to plead any of the foregoing identified in *Kimca I*.

Accordingly, the Court finds Plaintiffs fail to plead an economic injury under either a benefit of the bargain or price premium theory; therefore, they lack standing to pursue monetary damages for their alleged claims.

B. INJUNCTIVE RELIEF

In addition to monetary damages, Plaintiffs seek an order enjoining Defendant from selling the Baby Food Products. RC at pp. 96–97; *see also supra* note 2. Because they have not alleged a likelihood of continuing or future harm, however, Plaintiffs lack standing to seek this form of equitable relief.

“[W]hen seeking prospective injunctive relief, the plaintiff must prove the likelihood of *future or continuing harm.*” *Pungitore v. Barbera*, 506 F. App’x 40, 41 (2d Cir. 2012). Plaintiffs have not done so here. That Plaintiffs have been injured by their prior purchase of the Baby Food Products is insufficient, as “[p]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief.” *O’Shea*, 414 U.S. at 495–96. Further, Plaintiffs are now aware of the alleged omissions that they challenge, so there is no danger that they will be deceived by them in the future. *See generally Kimca I*, 2022 WL 1213488. Accordingly, because Plaintiffs failed to establish any likelihood of future or continuing harm, injunctive relief is inappropriate here.

C. PRIMARY JURISDICTION DOCTRINE

Defendant argues the FDA, not the Court through this class action, should determine what amounts of Heavy Metals are safe. Def. Mem. at 8. Accordingly, Defendant seeks dismissal of this case under the primary jurisdiction doctrine pending the FDA’s forthcoming determination on these issues. *Id.* Plaintiffs argue primary jurisdiction is not implicated because they do not allege Defendant’s products are adulterated and do not seek to impose labeling requirements, but instead

allege violations of consumer-protection laws related to deceptive marketing and advertising. Pl. Opp. at 7–12. Further, Plaintiffs argue, there are no regulations on labeling Heavy Metals in baby foods, nor is there any FDA ruling pending that would address it. *Id.* at 10.¹⁸ For the reasons stated below, the Court finds the FDA has primary jurisdiction over Plaintiffs’ claims.

The doctrine of primary jurisdiction “coordinate[s] administrative and judicial decision-making by taking advantage of agency expertise and referring issues of fact not within the conventional expertise of judges or cases which require the exercise of administrative discretion.” *Env’t Tech. Council v. Sierra Club*, 98 F.3d 774, 789 (4th Cir. 1996). The doctrine applies to claims “that contain some issue within the special competence of an administrative agency.” *In re Bulldog Trucking, Inc.*, 66 F.3d 1390, 1399 (4th Cir. 1995). The court must enable a “referral” to the agency by either staying the case to give the parties a “reasonable opportunity to seek an administrative ruling,” *id.*, or, if it would not prejudice the parties, dismissing the case without prejudice. *See Smith v. Clark/Smoot/Russell*, 796 F.3d 424, 431 (4th Cir. 2015). In this way, “primary jurisdiction serves judicial economy because the dispute may be decided by the administrative agency and obviate the need for court intervention.” *Cont'l Airlines, Inc. v. United Air Lines, Inc.*, 120 F. Supp. 2d 556, 574 (E.D. Va. 2000) (Ellis, J.) (internal quotations omitted).

The applicable factors and weight given to those factors varies by circuit. While the Fourth Circuit has no fixed formula for determining when the doctrine applies, it has generally focused on four factors: (i) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency’s particular field of

¹⁸ Plaintiffs also contend that any FDA action on Heavy Metals in baby food would be forward-looking and would not resolve Plaintiffs’ liability theories based on past deceptive conduct. *Id.* at 10. As discussed *infra*, any forthcoming FDA action would provide guidance on what constitutes a safe level of Heavy Metals in baby food, not determine the ultimate question of liability on Plaintiffs’ false advertising claims.

expertise; (ii) whether the question at issue is particularly within the agency’s discretion;¹⁹ (iii) whether there exists a substantial danger of inconsistent rulings; and (iv) whether a prior application has been made to the agency.²⁰ See *Cent. Tel. Co. of Va. v. Sprint Commc’ns Co. of Va., Inc.*, 759 F. Supp. 2d 772, 786 (E.D. Va. 2011) (Payne, J.), *aff’d*, 715 F.3d 501 (4th Cir. 2013); *Advantel, LLC v. Sprint Commc’ns Co.*, 105 F. Supp. 2d 476, 480–81 (E.D. Va. 2000) (Ellis, J.) (finding counterclaim that required a determination of whether a tariff was reasonable was within the FCC’s purview, but a claim to enforce tariff schedule was an action for enforcement of a contract within the ordinary competence of the courts). The Third Circuit applies factors nearly identical to those used in the Fourth Circuit. See *Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011). By contrast, the Ninth Circuit considers

- (1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration.

Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753, 760 (9th Cir. 2015). Under Ninth Circuit precedent, “efficiency is the deciding factor in whether to invoke primary jurisdiction.” *Id.* (internal quotations omitted).

District courts considering the applicability of the primary jurisdiction doctrine to cases arising out of the Congressional Reports have reached conflicting conclusions on this issue. In *In re Plum Baby Food Litigation*, the Northern District of California declined to find the FDA had

¹⁹ *Fisher v. Monster Beverage Corp.*, 656 F. App’x 819, 824 (9th Cir. 2016) (declining to exercise primary jurisdiction doctrine after finding alleged violations of consumer-protection laws related to deceptive marketing and advertising were not in the “sole purview of the FDA”); but see *Physicians Comm. for Resp. Med. v. Gen. Mills, Inc.*, No. 1:05-cv-958, 2006 WL 3487651, at *6 (E.D. Va. Nov. 30, 2006) (Brinkema, J.) (finding FDA had primary jurisdiction because, *inter alia*, “the FDA is authorized to regulate false or misleading labeling of food”).

²⁰ In addition to these four factors, Defendant includes a fifth factor considered by the Southern District of Florida that the Court finds inapplicable in this District. See Def. Mem. at 9–14; *Quidura v. Blackstone Labs, LLC*, No. 20-cv-80898, 2021 WL 4958789, at *3 (S.D. Fla. Mar. 8, 2021).

primary jurisdiction over claims that “Defendants fail to disclose to consumers that the Baby Foods contain (or have a material risk of containing) Heavy Metals, perchlorate, and/or other undesirable toxins or contaminants.” No. 4:21-cv-913 (Dkt. No. 98), ¶ 11 (N.D. Cal. Sept. 3, 2021); *id.* (Dkt. No. 125), at 2 (N.D. Cal. Jan. 12, 2022). Relying on Ninth Circuit precedent, the court noted that “uncertainty over how and when the FDA will act counsels against an indefinite stay.” *Id.* (Dkt. No. 125) at 2 (citing *Astiana*, 783 F.3d at 760); *see also id.* (Dkt. No. 131), Tr. at 28:20–25, 29:22.

Arriving at the opposite conclusion, the New Jersey state court in *Kimca v. Sprout Foods, Inc.*, found the FDA had primary jurisdiction over claims that Sprout’s packaging or marketing materials failed to “warn[] that its baby food products contained unsafe levels of dangerous toxic heavy metals.”²¹ *Kimca v. Sprout Foods, Inc.* (“*Kimca II*”), No. BER-L-002538-22, Compl. ¶ 38 (N.J. Super. Ct. Law. Div. May 10, 2022); *Kimca v. Sprout Foods, Inc.*, No. BER-L-002538-22, MTD Order at 4–7 (N.J. Super. Ct. Law Div. Aug. 17, 2022). In applying the Third Circuit’s four-factor test, the New Jersey state court found the case would require the Court to “determine what levels of heavy metals in baby foods are safe and acceptable, and whether it is misleading for foods containing certain levels of heavy metals to make true labeling statements about their contents.” *Kimca II*, MTD Order at 5 (cleaned up). These issues, the court found, were best left to the FDA’s expertise to determine and would promote “consistency of decision making.” *Id.* Because plaintiffs’ labeling claims were premised on the idea that any level of heavy metals in the baby foods was unsafe, similar to the claims here, “guidance from the FDA on what constitutes a safe level of heavy metals in baby food is integral to determining whether any of Sprout’s label statements were misleading.” *Id.* at 6.

²¹ The court also found that plaintiffs’ claims were substantially like those asserted and dismissed for lack of standing in plaintiffs’ federal lawsuit. *See Kimca II*, No. BER-L-002538-22 at 6.

Similarly, Fourth Circuit precedent weighs in favor of finding the FDA has primary jurisdiction over the issues in this case. *First*, while the ultimate question of Defendant's liability for alleged material omissions is within the conventional experience of the Court, resolution of Plaintiffs' claims depends on technical and policy considerations within the FDA's field of expertise. Plaintiffs' claims rest on three material omissions by Gerber: (1) disclosures that its Baby Food Products contained or were at a material risk of containing harmful Heavy Metals; (2) inadequate testing of, or failure to test for, all Heavy Metals in all its ingredients or finished products; and (3) allowing its Baby Food Products to be sold with harmful levels of Heavy Metals that, at times, failed to meet its own internal standards. RC ¶ 11. Plaintiffs argue their false advertising claims are firmly within the Court's expertise. Pl. Opp. at 8–10. Although the ultimate question of whether a company misled reasonable consumers by omitting material facts is routinely decided by courts and is not an area within the sole purview of the FDA, *see Fisher v. Monster Beverage Corp.*, 656 F. App'x 819, 824 (9th Cir. 2016), resolution of Plaintiffs' claims first requires a determination of whether the levels of Heavy Metals in Defendant's Baby Foods Products were harmful. Determining whether Defendant's products were at risk of containing *harmful* levels of Heavy Metals is a technical and policy consideration within the FDA's field of expertise that would be "appropriate and helpful in the pending litigation." *See CF Indus., Inc. v. Transcon. Gas Pipe Line Corp.*, 614 F.2d 33, 36 (4th Cir. 1980) (finding ultimate liability in the damages action was not within the agency's authority, but nonetheless concluding that agency expertise on the underlying issue would "be appropriate and helpful in the pending litigation").

Plaintiffs argue they do not seek to impose any labeling requirements that are inconsistent with federal laws; therefore, referral to the FDA is unnecessary. Pl. Opp. at 7. However, no tolerance level has been set and no labeling requirement exists for Heavy Metals in Defendant's

Baby Food Products.²² The Court is thus unable to conclude whether Defendant's labeling was misleading without guidance from the FDA on the Heavy Metals' toxicity. Further, resolution of the issue involves important policy considerations. For example, measures to limit toxic elements in foods may have "unintended consequences—like limiting access to foods that have significant nutritional benefits by making them unavailable or unaffordable for many families." (Dkt. No. 135-3) at 2.

Second, the question at issue is particularly within the FDA's discretion.²³ The FDA has the expertise to evaluate research and determine what levels of Heavy Metals can be considered harmful and whether consumers should be informed of their presence through labeling. *See Tran v. Sioux Honey Ass'n, Coop.*, No. 8:17-cv-110-JLS-JCGX, 2017 WL 5587276, at *2 (C.D. Cal. Oct. 11, 2017).²⁴ Further, the FDA has the authority to promulgate labeling requirements for food. *See* 21 U.S.C. § 343 (2021). "Congress plainly intended food labeling to be uniform in administration based on the FDCA's express preemption provisions with respect to food labeling." *See Tran*, 2017 WL 5587276, at *2 (citing 21 U.S.C. § 343–1(a)(2)–(3) (prohibiting any State or political subdivision of a State from establishing any requirement for the labeling of food of the type required by various sections of the FDCA)).

²² FDA's Closer to Zero action plan commits to proposing action levels for lead in categories of food consumed by babies in its first phase. "[S]ubsequent phases of this plan will include addressing additional toxic elements such as cadmium and mercury." (Dkt. No. 135-3) at 3.

²³ "[T]he FDA is authorized to regulate false or misleading labeling of food under 21 U.S.C. § 343(a)(1)." *Physicians Comm. for Resp. Med.*, 2006 WL 3487651, at *6.

²⁴ Plaintiffs' attempt to distinguish *Tran* is unavailing. They argue their claims are based on whether a reasonable consumer would want to know whether the Baby Food Products contain Heavy Metals and that reasonable consumers "would want to avoid risking the health of their children," Pl. Opp. at 10–11, whereas in *Tran*, "the court stayed the case based on the plaintiff's concession that the claims depended on 'what constitutes a safe level of glyphosate in honey' and on a concurrent Environmental Protection Agency review of the chemical and its health risks." *Id.* at 10 (citing *Tran*, at *2–3). As discussed above, Plaintiffs' claims depend on what constitutes a safe level of Heavy Metals and a concurrent FDA review of Heavy Metal amounts in baby food and their health risks.

The FDA is presently working on its Closer to Zero Plan that identifies actions the agency will take over the next few years to reduce exposure to Heavy Metals. “Through the Closer to Zero Plan, over the course of the next several years and well beyond 2024, the FDA has set a goal of setting action levels for Heavy Metals.” Pl. Opp. at 8 (citing Dkt. No. 135-4). To date, the FDA has set action levels for inorganic arsenic in infant rice cereal,²⁵ lowered the Interim Reference Level for lead in foods, and “issued draft guidance to industry on action levels for lead in single-strength juices and juice blends.” See “Closer to Zero: Action Plan for Baby Foods,” FDA (current as of June 29, 2022), <https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods> (last accessed Sept. 19, 2022). Further, the FDA received \$18 million for Fiscal Year 2022 “to establish reference levels for exposure to toxic elements from foods . . . and provide action levels with the expectation that . . . they will decrease over time for lead, arsenic, cadmium, and mercury for different categories of foods consumed by babies and very young children.” (Dkt. No. 135-14) at 1, 11.

Plaintiffs argue that action levels “are not determinations that there are no health hazards or risks,” Sur-Reply at 2, and “are not binding, but are based on what is achievable (which is why they are not called safe levels).” Pl. Opp. at 8. They argue that levels of inorganic arsenic, for example, below the FDA’s action levels do not necessarily mean the product is safe or poses no health risk. Sur-Reply at 2 (citing *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 252–53 (3d Cir. 2008)). Therefore, Plaintiffs implicitly argue FDA action levels on the Heavy Metals have no bearing on the litigation.

²⁵ See “Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants,” FDA (current as of Feb. 25, 2022), <https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants> (last accessed Sept. 20, 2022).

The Court finds this argument unpersuasive. When any “poisonous or deleterious substance added to any food” cannot be avoided, the FDA is required to promulgate regulations limiting the quantity therein or to the extent necessary for the protection of public health. 21 U.S.C. § 346 (2021). According to the FDA,

Action levels are levels set by the FDA to provide guidance to industry and FDA field staff. They are a level of contamination at which a food may be regarded as adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act. The agency considers action levels, in addition to other factors, when considering whether to take compliance or enforcement action in a particular case. Action levels can be lowered over time as appropriate.

(Dkt. No. 135-3) at 2. Put another way, “[a] reference level is a measure of exposure to a substance from food that the FDA may use to determine if the amount of exposure to an individual substance across foods could result in a specific health impact.” (Dkt. No. 135-14) at 11.

Plaintiffs allege that the FDA’s 100 ppb action level for inorganic arsenic in infant rice cereal is “too high to adequately protect infants and children” and levels below the FDA’s action level are nonetheless harmful. RC ¶ 52; *see id.* ¶ 109. It is important to note that the “FDA’s testing has shown there [is] no immediate health risk to children from exposure to toxic elements at the levels currently found in food.” (Dkt. No. 135-12) at 14. Plaintiffs ask the Court to substitute its judgment on what levels of Heavy Metals in baby food are safe for the FDA’s judgment. This type of scientific determination is particularly within the FDA’s discretion and expertise.

Third, the substantial danger of inconsistent rulings also weighs in favor of finding the FDA has primary jurisdiction. Cases are proceeding against several baby food producers, including Defendant Gerber, Hain Celestial Group, Inc.,²⁶ Plum, PBC,²⁷ and Beech-Nut Nutrition

²⁶ *In re Hain Celestial Group Heavy Metals Baby Food Litig.*, No. 2:21-cv-00678-JS-AYS (E.D.N.Y.).

²⁷ *In re Plum Baby Food Litig.*, No. 4:21-cv-00913-YGR (N.D. Cal.).

Company.²⁸ Any decision by the Court regarding what level of Heavy Metals is harmful enough to require a warning label on the Baby Food Products will likely result in a patchwork of decisions that vary by location, court, manufacturer, and product, resulting in different labeling standards for substantially similar baby food products produced by different manufacturers.

Lastly, the Court is not aware that the parties have made any previous application to the FDA on the issues before the Court. This weighs against finding the FDA has primary jurisdiction. However, considering the strength of the other factors, this Court finds the FDA has primary jurisdiction to determine whether the amount of Heavy Metals in the Baby Foods Products is harmful. Because the Court lacks jurisdiction to hear this case, it need not determine whether a stay or dismissal with prejudice would best “provide[] the parties a reasonable opportunity to seek an administrative ruling.” *Stevens v. Boston Sci. Corp.*, 152 F. Supp. 3d 527, 534 (S.D.W. Va. 2016).

IV. CONCLUSION

For the reasons stated above, the Court GRANTS Defendant’s Motion to Dismiss (Dkt. No. 132). Accordingly, it is hereby

ORDERED that Plaintiffs’ Representative Complaint (Dkt. No. 112) is DISMISSED WITHOUT PREJUDICE.

It is SO ORDERED.

/s/

Hon. Michael S. Nachmanoff
United States District Judge

October 17, 2022
Alexandria, Virginia

²⁸ *In re Beech-Nut Nutrition Co. Baby Food Litig.*, No. 1:21-cv-00133-DNH-CFH (N.D.N.Y.).